DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 27, 2013

Innovative Medical Technologies, Incorporated
Mr. Brad Brown
President
15059 Cedar Street
LEAWOOD KS 66224

Re: K123987
Trade/Device Name: Improve Blood Collection Set and Improsafe Blood Collection Set
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 24, 2013
Received: July 26, 2013

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number : K123987

Device Name: Improve Blood Collection Set and Improsafe Blood Collection Set

Indications for Use: Improve Blood Collection Set and Improsafe Blood Collection Set are winged blood collection needles with flexible tubing and a female luer adapter intended for venipuncture to obtain blood samples from patients. Some reorder numbers are provided with a male luer adapter. The male luer adapter contains a non- patient needle end for puncturing the stopper of an evacuated blood collection tube. Those without a male luer adapter are provided with a protective cap on the end of the female luer adapter.

The Improsafe Blood Collection Set is provided with an attached safety shield for covering the used needle prior to disposal. After withdrawal of the needle from the patient's vein, the attached safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needle stick.

The Improve Blood Collection Set and Improsafe Blood Collection Set is also indicated for short-term (up to 2 hours) intravenous administration of fluids and may be used for any patient population with consideration given to patient size, appropriateness for the solution being infused and duration of therapy. For devices that include the male luer adapter: after removing the attached male luer adapter from the blood collection set, connect the female luer adapter to a syringe or other compatible/appropriate device.

Prescription Use _____YES_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____NO_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
2013.08.27 15:03:31
-04'00'

(Division Sign-Off)

Division of Anesthesiology, General Hospital

Respiratory, Infection Control and

Dental Devices

510(k) Number: _____